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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

20350 7590 03/19/2003

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,410	SAWADA ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgement of Papers Received: Information Disclosure Statement entered 12/16/02 and Amendment/Response entered 12/16/02.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (EP 0 661 045) in view of Taniguchi et al (EP 0 709 386) both in further view of Wong et al (USPN 5,391,381) and Kawata et al (USPN 4,404,183). Claims 1 – 20 and 23 – 26 are drawn to a time-released compressed layered tablet. The core comprises erodible fillers, while the outer layer is made from a hydrogel-forming polymer and a hydrophilic base. The erodible filler is selected from malic, citric and tartaric acid, polyethylene glycol sucrose, and lactulose. The hydrogel-forming polymer contains a type of polyethylene oxide. The hydrophilic base is selected from polyethylene glycol sucrose, and lactulose. Claims 21 – 24 are drawn to method of alleviating drug interactions.

As discussed in prior action Nakashima et al discloses coated tablet for absorption into the upper digestive tract. The outer layer of the tablet comprises a hydrogel and a hydrophilic base, while the core can comprise various excipients including fillers such as polyethylene glycol

(pg. 3, lin. 30 – pg. 4, lin. 6). The core of the tablet diminishes, yet the reference does not disclose what percentage is eroded.

What is lacking in the reference is a teaching to the specific drug and minor excipients such as red and/or yellow oxide. Wong shows the level of skill in the art that is known to combine tables delivering active agents comprising polyethylene and red ferric oxide (Examples). Taniguchi discloses a fused benzazepine derivative that can be formulated into tablet using conventional excipients including sucrose, gelatin and hydroxypropylcellulose. With regard to the other possible fillers recited by claims 5 and 6, Kawata, et al provides evidence to the level of skill in the art to combine and use such excipients in coated tablets similar to that of the invention.

With regard to claims 15 – 19, which recite various characteristics of the active agent, it is the position of the examiner that these claims are non-critical to the patentability of the claimed invention. The properties are inherent to the formulation of Taniguchi, the drug of claims 20 and 26, and thereby do not distinguish the claimed invention from the prior art.

With regard to claims 24 and 25, which recite improvements comprising the preparation as previously described by applicant, it is the position of the examiner that these claims are too obviated by the prior art. Nakashima provides the compression molded hydrophilic base/hydrogel-forming polymer tablet. The core of the tablet of Nakashima comprises polyethylene glycol, which possesses sufficient erosion and solubility properties to carry out the modes of the invention. Given the wide range of drugs useful with the preparation, one of ordinary skill in the art would be able to incorporate a drug into the core and another into the

surrounding area. Though a percentage of erosion is not recited, this erosion is inherent to the excipient chosen, and can be further refined through routine experimentation.

With these aspects in mind one of ordinary skill in the art would have been motivated to combine the suggestions and teachings in the art. A skilled artisan would have been motivated to combine the hydrophilic base/hydrogel-forming polymer preparation with the drug of Taniguchi in order to provide a sustained release profile for the drug to the lower intestinal tract. Following the knowledge on the art the skilled artisan could have substituted any number of excipients including those of Wong or Kawata into the preparation in order to add an aesthetic appeal or better erosion properties. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings and suggestion in this way, with an expected result of sustained release oral tablet capable of treating various renal and cardiovascular disorders.

Response to Arguments

4. Applicant's arguments filed 12/10/02 have been fully considered but they are not persuasive. Applicant argues:

a. No motivation to modify the references

b. No reasonable expectation of Success

c. Cited references do not teach each and every limitation of the claims.

With regard to argument a., applicant makes a point that Nakashima does not disclose an erodible core. Yet as discussed in the above rejection, the reference discloses that the core diminishes, yet does not disclose the percentage (pg. 6, lin. 30 – 33). In applicant's claims, the

limitation is to erodible filler ***capable*** of eroding 40% – 90% (claim 1). Applicant later discloses that polyethylene glycol is such erodible filler ***capable*** of eroding to this percentage (claim 5). The limitation that something is ***capable*** of achieving a particular parameter is not a positive limitation and does not distinguish the limitation from the prior art. It is the position of the examiner that one of ordinary skill in the art, with the same constituents of applicant, be able to determine through routine experimentation at what particular percentage the filler core would best erode to achieve the best drug delivery. A skilled artisan working with the combination of Nakashima (polyethylene glycol core, hydrogel-forming polymer/hydrophilic base coating) where the core has been designated by applicant as being ***capable*** of eroding to the needs of the applicant, would be able to modify and optimize the formulation.

With regard to argument b., applicant points to the deficiencies in Nakashima that are remedied by the supporting references. Wong is applied to show the level of skill in the art that is known to produce tablet formulations comprising polyethylene glycol and red ferric oxide. Similarly, the Taniguchi teaches the specific active agent which a skilled artisan would be able to substitute into the formulation of Nakashima under the reference's suggestion to a wide range of active agents including anti-inflammatory and CNS affecting agents. Kawata is added to show the level of skill in the art in combining the remaining fillers with coatings materials and drugs as claimed by applicant. As discussed it would have been obvious to a skilled artisan, seeing that such combination were possible and successful, to expect the combination suggested by the examiner (the tablet formulation of Nakashima comprising the hydrophilic base/hydrogel-forming polymer preparation, the drug of Taniguchi, and the excipients of Wong and Kawata) would yield a controlled release tablet capable of treating various disorders.

With regard to argument c. applicant is reminded that the reference are not required to teach every element of the invention in order to render it obvious. The suggestion must be present, and that is what has been discussed in the above and prior actions. Had the references taught a 40-90% erodible core, they would have been used as anticipatory (*35 USC 102*) rather than obviating (*35 USC 103*) art. The fact that the claims are drawn to a tablet where the core is ***capable*** of eroding from 40 – 90%, means that all a skilled artisan would need to arrive at the invention would be the constituents of the core, and experimental research. With all of this taken into consideration, the claims will remain rejected as being obvious, and non-distinctive from the prior art.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
March 17, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600